



Senate

General Assembly

File No. 384

February Session, 2016

Substitute Senate Bill No. 371

Senate, March 31, 2016

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE USE OF EXPERIMENTAL DRUGS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2016*) (a) For purposes of this
2 section:

3 (1) "Investigational drug, biological product or device" means a
4 drug, biological product or biological device that has successfully
5 completed a phase one clinical trial of the federal Food and Drug
6 Administration but has not yet been approved for general use by the
7 federal Food and Drug Administration and remains under
8 investigation in a clinical trial approved by the federal Food and Drug
9 Administration;

10 (2) "Patient" means a person who has a terminal illness, verified by
11 the person's treating physician, who is not being treated as an inpatient
12 in a hospital licensed under chapter 368v of the general statutes;

13 (3) "Treating physician" means a physician licensed under chapter

14 370 of the general statutes who has primary responsibility for the
15 medical care of the patient and treatment of the patient's terminal
16 illness; and

17 (4) "Terminal illness" means a medical condition that a patient's
18 treating physician anticipates, with reasonable medical judgment, will
19 result in the patient's death or a state of permanent unconsciousness
20 from which recovery is unlikely within a period of one year.

21 (b) A patient is eligible to receive treatment with an investigational
22 drug, biological product or device if the patient has (1) considered all
23 other treatment options currently approved by the federal Food and
24 Drug Administration, (2) been unable to participate in a clinical trial
25 for the terminal illness that is not more than one hundred miles from
26 the patient's home address, or not been accepted to a clinical trial not
27 more than one week after completion of the clinical trial application
28 process, (3) received a recommendation from his or her treating
29 physician for an investigational drug, biological product or device, (4)
30 given written, informed consent, as provided in subsection (c) of this
31 section, for the use of the investigational drug, biological product or
32 device or, if the patient is a minor or lacks the mental capacity to
33 provide informed consent, a parent of the minor or a legal guardian of
34 the minor or adult patient has given such written, informed consent on
35 the patient's behalf, and (5) obtained written documentation from his
36 or her treating physician stating that the patient meets the
37 requirements of this subsection.

38 (c) A patient gives written informed consent when the patient, or if
39 the patient is a minor or lacks the mental capacity to provide informed
40 consent, a parent of the minor or the legal guardian of the minor or
41 adult patient, signs a written document, verified by the patient's
42 treating physician and a witness that, at a minimum: (1) Explains the
43 currently approved and conventionally recognized products and
44 treatments for the terminal illness from which the patient suffers; (2)
45 confirms the patient's concurrence with his or her treating physician in
46 believing that all currently approved and conventionally recognized

47 products and treatments are unlikely to prolong the patient's life; (3)
48 clearly identifies the specific proposed investigational drug, biological
49 product or device with which the patient is seeking to be treated; (4)
50 describes the potentially best and worst outcomes of using the
51 investigational drug, biological product or device with a realistic
52 description of the most likely outcome, including the possibility that
53 new, unanticipated, different or worse symptoms might result and that
54 death could be hastened by the proposed treatment, based on the
55 treating physician's knowledge of the proposed treatment in
56 conjunction with an awareness of the patient's condition; (5) states
57 clearly that the patient's health carrier, as defined in section 3 of this
58 act, treating physician or other health care provider is not obligated to
59 pay for any care or treatments resulting from the use of the
60 investigational drug, biological product or device; (6) states clearly that
61 the patient's eligibility for hospice care may be withdrawn if the
62 patient begins treatment with an investigational drug, biological
63 product or device but that hospice care may be reinstated if such
64 treatment ends and the patient meets hospice eligibility requirements;
65 (7) states clearly that in-home health care may be denied if such
66 treatment begins; and (8) states that the patient understands that the
67 patient is liable for the costs of, or associated with, the investigational
68 drug, biological product or device and that this liability extends to the
69 patient's estate, unless a contract between the patient and the
70 manufacturer of the investigational drug, biological product or device
71 states otherwise.

72 (d) Notwithstanding the provisions of chapter 370 of the general
73 statutes, the Department of Public Health or the Connecticut Medical
74 Examining Board shall not revoke, fail to renew, suspend or take any
75 disciplinary action against a physician based solely on the treating
76 physician's recommendation to a patient regarding access to, or
77 treatment with, an investigational drug, biological product or device,
78 provided such recommendation is consistent with medical standards
79 of care.

80 (e) No official, employee or agent of the state shall prevent, or

81 attempt to prevent, a patient who is eligible under subsection (b) of
82 this section from accessing an investigational drug, biological product
83 or device.

84 (f) Nothing in this section shall create a cause of action against the
85 patient's treating physician or any other person or entity involved in
86 the care of a patient being treated with an investigational drug,
87 biological product or device for any harm done to such patient
88 resulting from the investigational drug, biological product or device.

89 Sec. 2. (NEW) (*Effective October 1, 2016*) (a) A manufacturer of an
90 investigational drug, biological product or device, as defined in section
91 1 of this act, may make available the manufacturer's investigational
92 drug, biological product or device to a patient who is eligible under
93 subsection (b) of section 1 of this act and may (1) provide the
94 investigational drug, biological product or device to such patient
95 without receiving compensation, or (2) require such patient to pay the
96 costs of, or associated with, the manufacture of the investigational
97 drug, biological product or device.

98 (b) Nothing in this section shall create a cause of action against a
99 manufacturer of an investigational drug, biological product or device
100 that makes available such investigational drug, biological product or
101 device to an eligible patient for any harm done to such patient
102 resulting from the investigational drug, biological product or device.

103 Sec. 3. (NEW) (*Effective October 1, 2016*) (a) As used in this section,
104 "health carrier" means an insurance company, health care center,
105 hospital service corporation, medical service corporation, fraternal
106 benefit society or other entity that delivers, issues for delivery, renews,
107 amends or continues a health insurance policy providing coverage of
108 the type provided in subdivisions (1), (2), (4), (11), (12) and (16) of
109 section 38a-469 of the general statutes in this state.

110 (b) A health carrier may provide coverage for an investigational
111 drug, biological product or device, as defined in section 1 of this act,
112 that is made available pursuant to section 2 of this act to an insured

113 patient who is eligible under subsection (b) of section 1 of this act.

114 (c) A health carrier may deny coverage to an insured patient from
115 the time such patient begins treatment with the investigational drug,
116 biological product or device for a period not to exceed six months from
117 the date such patient ceases treatment with the investigational drug,
118 biological product or device, except that coverage may not be denied
119 for a preexisting condition or for coverage for benefits that commenced
120 prior to the date such patient begins such treatment.

121 (d) Nothing in this section shall affect the provisions of sections 38a-
122 504a to 38a-504g, inclusive, and 38a-542a to 38a-542g, inclusive, of the
123 general statutes concerning insurance coverage for certain costs
124 associated with clinical trials. Treatment with an investigational drug,
125 biological product or device is not considered a clinical trial for the
126 purposes of said sections.

127 (e) Nothing in this section shall create a cause of action against a
128 health carrier that provides coverage for an investigational drug,
129 biological product or device pursuant to subsection (b) of this section,
130 or denies coverage in accordance with subsection (c) of this section, to
131 an insured patient who begins treatment with an investigational drug,
132 biological product or device.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2016	New section
Sec. 2	October 1, 2016	New section
Sec. 3	October 1, 2016	New section

Statement of Legislative Commissioners:

In Section 1(a)(1), "phase one of a clinical trial" was changed to "a phase one clinical trial of the federal Food and Drug Administration" for statutory consistency; in Section 1(a)(2), "patient's treating physician, and" was changed to "person's treating physician, who" for consistency with standard drafting conventions; in Section 1(b)(5), "written documentation" was changed to "obtained written documentation" for clarity; and in Section 1(c)(1) and (2), "currently

approved products and treatments" and "currently approved and conventionally recognized treatments", respectively, were changed to "currently approved and conventionally recognized products and treatments" for internal consistency.

INS *Joint Favorable Subst. -LCO*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact: None

Municipal Impact: None

Explanation

The bill is not anticipated to result in a cost to the state employee plan or municipal health plans as the bill does not require health plans to provide coverage for investigational drugs, biological products or devices. In addition, the bill does not create a private cause of action against a health carrier that provides or denies coverage for an insured patient being treated with an investigational drug.

The Out Years

State Impact: None

Municipal Impact: None

OLR Bill Analysis**sSB 371*****AN ACT CONCERNING THE USE OF EXPERIMENTAL DRUGS.*****SUMMARY:**

This bill allows certain terminally ill patients, under specified conditions, to access medications and devices not approved for general use by the federal Food and Drug Administration (FDA). The bill applies to investigational drugs, biological products, or devices (hereinafter “investigational drugs”) that have completed Phase 1 of an FDA-approved clinical trial and are still part of the trial. To qualify for the program, patients must meet certain eligibility criteria and complete a detailed informed consent document.

The bill allows investigational drug manufacturers to provide eligible patients with investigational drugs. Manufacturers can charge eligible patients for the investigational drugs they provide. The bill allows health carriers (e.g., insurers and HMOs) to cover investigational drugs, and it specifies when carriers can deny coverage to patients being treated with them.

The bill specifies that it does not create a private cause of action against (1) an investigational drug manufacturer, the treating physician, or other people or entities involved in the patient’s care for any harm caused by an investigational drug or (2) a health carrier that provides or denies coverage for an insured patient being treated with an investigational drug.

The bill prohibits the Department of Public Health and Medical Examining Board from taking any disciplinary action against a physician based solely on his or her recommendation to a patient to access or use an investigational drug, as long as the recommendation is consistent with medical standards of care. It also prohibits state

officials, employees, and agents from preventing or attempting to prevent an eligible patient from accessing an investigational drug.

Federal law vests in FDA the authority to approve drugs before they can be sold. FDA has a separate process to make investigational drugs available outside of a clinical trial before all phases of the trial are complete. Under this process (called “expanded access”), the patient’s physician must submit a request to FDA for approval (see BACKGROUND).

EFFECTIVE DATE: October 1, 2016

INVESTIGATIONAL DRUGS

Patient Eligibility

The bill allows manufacturers to provide terminally ill patients with investigational drugs under certain conditions. It defines a “terminal illness” as a medical condition that the treating physician anticipates, with reasonable medical judgment, will result in a patient’s death or a state of unconsciousness from which recovery is unlikely within a year.

Under the bill, to be eligible to receive treatment with an investigational drug, a patient must:

1. have a terminal illness verified by his or her treating physician (i.e., a state-licensed physician with primary responsibility for the patient’s medical care and treatment of the terminal illness);
2. not be a hospital inpatient;
3. have considered all other FDA-approved treatment options;
4. be unable to participate in a clinical trial within 100 miles of his or her home, or not be accepted into a clinical trial no more than a week after the end of the trial application process;
5. receive a recommendation for the drug from his or her treating physician;

6. give written informed consent for the drug's use (see below);
and
7. obtain from the treating physician written documentation that the patient meets requirements (3) through (6).

Informed Consent

Under the bill, the required informed consent document must be verified by the treating physician and a witness. The patient must sign the document, except if the patient is a minor or lacks the capacity to provide informed consent, in which case the minor's parent or patient's legal guardian must consent on the patient's behalf.

The document must:

1. explain the currently approved and conventionally recognized products and treatments for the terminal illness;
2. verify that the patient agrees with the treating physician in believing that all currently approved and conventionally recognized products and treatments are unlikely to prolong the his or her life;
3. clearly identify the specific proposed investigational drug with which the patient is seeking treatment;
4. describe the potentially best and worst outcomes of using the drug with a realistic description of the most likely outcome, including the possibility that new, unanticipated, or worse symptoms may result and that the treatment could hasten death, based on the physician's knowledge of the treatment and awareness of the patient's condition; and
5. state that the patient understands that he or she is liable for the costs of, or associated with, the drug and that this liability extends to the patient's estate, unless a contract between the patient and the manufacturer provides otherwise.

The document must also clearly state that:

1. the patient's health carrier, treating physician, or other providers are not obligated to pay for any care or treatment resulting from taking the investigational drug;
2. the patient's hospice care eligibility may be withdrawn if the patient begins treatment with an investigational drug, but hospice care may be reinstated if the treatment ends and the patient is hospice eligible; and
3. in-home health care may be denied if treatment begins.

Insurance Provisions

Under the bill, health carriers may cover investigational drugs made available to eligible patients as set forth above but are not required to do so. While a patient is being treated with an investigational drug and for the following six months, carriers may deny coverage to the patient, except for (1) preexisting conditions or (2) benefits that began before treatment with the drug.

The bill defines a "health carrier" as an insurer, HMO, hospital or medical service corporation, fraternal benefit society, or other entity that delivers, issues, renews, amends, or continues a health insurance policy that covers (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; (4) hospital or medical services; or (5) ancillary services, such as dental, vision, or prescription drugs.

The bill specifies that (1) treatment with investigational drugs as set forth in the bill is not considered a clinical trial for purposes of the law's requirements for insurance coverage of certain clinical trial costs and (2) it does not affect those requirements.

BACKGROUND

FDA Drug Approval Process and Expanded Access

Drug companies wanting to sell a new drug in the United States must receive FDA approval. The approval process involves several

steps, including clinical trials.

For individual patients seeking access to investigational drugs that have not yet received FDA approval, a physician can apply to FDA under the “expanded access” process. Federal law and regulations specify the conditions under which FDA can grant such access. Among other things, FDA must determine that:

1. the patient has a serious or immediately life-threatening condition and there is no comparable or satisfactory alternative therapy;
2. the potential benefit justifies the potential risks and those risks are not unreasonable in the context of the condition; and
3. providing the drug for the requested use will not interfere with clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of that use (21 C.F.R. § 312.305).

Even where FDA grants approval, manufacturers are not required to provide the drug.

Related Bill

The Public Health Committee favorably reported a similar bill (sHB 5270) on patient access to investigational drugs.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable

Yea 19 Nay 0 (03/15/2016)